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EXAMINER

SAYDAH, J

ART UNIT

PAPER NUMBER

3764

DATE MAILED:

09/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
08/753,929

Applicant(s)

Rothschild et al.Examiner
Jayne SaydahGroup Art Unit
3764☒ Responsive to communication(s) filed on Jul 16, 1999☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-37 is/are pending in the application.Of the above, claim(s) 6-8, 11-13, 16, 19-23, and 28-37 is/are withdrawn from consideration.☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-3, 9, 10, 15, 17, 18, and 24-27 is/are rejected.☒ Claim(s) 4, 5, and 14 is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☒ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The Examiner reviewed the most recent prior Office Action, Paper No. 17 and agrees with the applicant that the claim rejections using 35 USC 102(b) were inappropriate. It appears as though the previous Examiner made an inadvertent typographical error. We apologize for any inconvenience or confusion this may have caused.

The Examiner also agrees that the use of Whiteside [5,022,390] is inapplicable to Claims 1, 13, 15 and 27. Whiteside discloses a method of forming a natural foot orthosis for providing support for a lower extremity. Whiteside fails to disclose bonding thermoformable plastic sheets together. Claims 1-3, 9,10, 15, 17, 18 and 24-27 are rejected under new grounds, as discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruscito et al. [5,573,501]. Ruscito et al. disclose a method of forming a foot orthosis comprising the following steps: forming a positive mold of the lower extremity (see column 4, line 33, column 6, 61); positioning a thermoformable plastic material around the mold (see column 4, line 55, 59-60, column 5, line 1, 3-6, 39-53, column 6, lines 48-54); wrapping a thermoformable plastic sheet

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around said positive mold (see column 5, line 1, column 5, lines 3-6, 8-10, 39-53); vacuum sealing the thermoformable plastic sheet around the mold so that the thermoformable plastic material and sheet bond together (see column 5, lines 58-63); and trimming the mold (see column 6, line 19). Ruscito et al. do not disclose positioning the thermoplastic material around predetermined locations on the positive mold, but it would have been obvious to one skilled in the art to put the material on predetermined locations to ensure that the mold is fitted to the proper portions of the users foot and leg. Ruscito et al. also do not disclose the cooling of the mold, but it is inherent in the art of plastics molding that a cooling step must occur.

Regarding claims 2 and 3, Ruscito et al. disclose making the brace from various compounds including polyethylene and polypropylene (see column 6, line 8-13 and 53-54). Ruscito et al. does not disclose the specific ratio of 90-10 or 93-7 of polypropylene to polyethylene. However, absent a statement of criticality, it would have been obvious to one having ordinary skill in art at the time the invention was made to use the claimed materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Regarding claim 9, Ruscito et al. discloses a thermoformable plastic material strip in column 5, lines 7-11. Ruscito et al. does not disclose the specific dimensions as claimed, but depending upon the specific size of the user and area to be reinforced, it would have been obvious to person of ordinary skill in the art to use similar dimensions.

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Regarding claim 10, Ruscito et al. discloses placing reinforcing strips of thermoformable material on the ankle and plantar portions of the brace and stress points in general. Ruscito et al. does not specifically state that the distal end of the strip is centered on the longitudinal arch on the positive mold and the strip is adapted to extend below the malleoli posterior of the positive mold, above the tendon region of the positive mold and centered proximal over an edge of the positive mold. However, since Ruscito et al. recognizes the use of reinforcing strips in these general areas, it would have been obvious to a person of ordinary skill in the art to use the reinforcing strips in this manner.

Regarding claims 17 and 18, see discussion of claims 2 and 3 above.

Regarding claims 24, 25, 26 and 27, as discussed above Ruscito et al. disclose using reinforcing strips of thermoplastic material in areas of stress and the ankle and plantar areas of the foot and lower leg. It would have been obvious to one skilled in the art to use the strips in the manner claimed because the areas supported by the strips are the ankle, plantar surface of the foot and the general areas of stress.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Ruscito et al. [5,573,501]. Ruscito et al. disclose a foot orthosis comprising a rigid support structure [10,14] formed of thermoformable plastic material (see column 4, line 55, 59-60, column 5, line 1, 3-6, 39-53, column 6, lines 48-54) bonded to a sheet of thermoformable plastic material (see column 5, lines 58-63) and the support structure has reinforced areas created by strips of thermoformable plastic material (see column 5, lines 7-11).

Allowable Subject Matter

Claims 3, 4 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication should be directed to Jayne Saydah at telephone number (703)306-5572.



**RICHARD APLEY
SUPERVISORY PATENT EXAMINER
ART UNIT 3764**